UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,945	03/27/2001	Hsuan-Yin Lan-Hargest	12938-002001	5280

7590 04/23/2002

HAROLD H. FOX
Fish & Richardson P.C.
601 Thirteenth Street, N.W.
Washington, DC 20005

EXAMINER	
BAHAR, MOJDEH	
ART UNIT	PAPER NUMBER
1617	6

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/812,945	Applicant(s) LAN-HARGEST ET AL.	
	Examiner Mojdeh Bahar	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *3,8,9,11,13-16,19-39 and 47-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7,10,12,17,18 &40-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's response to the office action of November 6, 2001, submitted February 6, 2002 is acknowledged. Applicant's remarks are persuasive to remove the rejection under 35 USC 101/112, 1st paragraph (written description).

Applicant has argued that Groups I and II should be rejoined. Note that the invention in Groups I and II are distinct since they have different functions, i.e., inhibition of histone deacetylase vs. treatment of cancer.

Applicant timely traversed the restriction requirement in Paper No. 5.

The restriction requirement is still deemed proper and is made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-7, 10, 12, 17-18, 40-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some types of cancer, does not reasonably provide enablement for "treating cancer" in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Given the current state of the art, the treatment of all cancers broadly is unpredictable. One of ordinary skill in the art would not believe that one compound could treat all types of cancer with a single therapeutic agent. Decisional law would seem to indicate that when the utility in question is sufficiently unusual an examiner is justified in requiring substantiating evidence, *In re Buting*, 163 USPQ 689 (1969).

Moreover, one of ordinary skill in the art would not know which cancers could appropriately be treated with the claimed compounds and would be required to perform undue experimentation to determine the effectiveness and suitability of the claimed compounds in the treatment of different types of cancer. The Skilled Artisan would view cancer as a group of maladies not treatable with one medicament or therapeutic regimen.

The Skilled Artisan would view cancer as a group of maladies not treatable with one medicament or therapeutic regimen.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-7, 10, 12, 17-18, 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richon et al. and Marks et al.

Richon et al. teaches that hydroxamic acid derivatives, a class of hybrid bipolar compounds (HPCs) induce terminal differentiation and or apoptosis in various transformed cells, see abstract.

Marks et al. teaches that hydroxamic acid-based HPCs are potentially effective agents for cancer therapy, see abstract (reference FF of IDS).

Richon et al. and Marks et al. do not explicitly teach the elected compound in their method of treating cancer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected compound in a method of treating cancer.

One of ordinary skill in the art would have been motivated to employ the elected compound in a method of treating cancer because the elected compound is a hydroxamic acid derivative. The Skilled Artisan would reasonably expect the elected compound, a derivative of hydroxamic acid to exhibit therapeutic effects similar to hydroxamic acid because structurally related compounds would have been expected to have similar therapeutic effects.

Response to Arguments

Applicant's arguments filed February 6, 2002 have been fully considered but they are not persuasive.

Applicant's first argument is that the enablement rejection should be withdrawn since applicant has claimed a method of inhibiting histone deacetylase activity in cells. Note that independent claim 1 recites "a method of inhibiting histone deacetylase [...] activity in cells, thereby treating one or more disorders [...]". In the specification Cancer is named as one of the disorders to be treated via the applicant's method. The treatment of all types of cancer (as understood by the generic word cancer) is not enabled by the specification. Also note that the applicant has elected cancer as the disorder to be treated.

Applicant argues that the claimed invention is non-obvious over the prior art because the exact compounds of formula I (claim 1 herein) are not taught in the prior art references. Note that the both references indicate that the anti-cancer activity as well as the HDAC inhibitory activity of hydroxamic acid compounds are known. Moreover, Marks et al. provides a guide in choosing hydroxamic acid derivatives that would exhibit theses therapeutic activities:

> "The essential characteristics of hydroxamic-acid based HPCs are a polar site, the hydroxamic group, a six-carbon hydrophobic methylene spacer, a second polar site and a terminal hydrophobic group" (see page 1212, second column).

Now, consider the following example: compounds of formula I have the two polar sites (i.e., when X1 is an O and when Y1 is O-C(O)-O), the hydroxamic Group is present in formula 1 compounds when X2 is NHOH and X1 is an O, L and Y2 together can form the spacer when L is a 5 carbon chain and Y2 is a CH2, a terminal hydrophobic group is present when A is a benzene ring. Therefore, formula I compounds do follow the requirements set forth in Marks et al.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
April 17, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200